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This Office action is in response to Applicants' remarks received August 26, 2010.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 1-66, 75-191 are canceled. Claims 67-74 are currently under examination.

Priority: The request for priority to provisional application 60/550,014, filed March 3, 2004, is acknowledged.

### **Objections and Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 67-69, 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Waugh et al. (WO 0207773). Waugh et al. disclose a composition comprising a non-covalent association complex of a positively charged-charged backbone polymer having positively charged branching groups attached thereto, wherein said polymer is polylysine and the positively charged branching group can be a HIV-TAT fragment having the formula (gly)<sub>p</sub>-RGRDDRRQRRR-(gly)<sub>q</sub> or (gly)<sub>p</sub>-YGRKKRRQRRR-(gly)<sub>q</sub>, wherein the subscripts p and q are

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each independently an integer from 0 to 20 (p. 6-9). The composition can be used for topical delivery (p. 19). Waugh et al. also teach a method of topically delivering said composition comprising a biological agent and a therapeutic agent to a subject (p. 40 lines 1-16; claims 67-69, 71, 73-74). Waugh et al. teach that said therapeutic agent can be cosmetic agents, including BOTOX (antiwrinkle agent) (p. 15; claims 67-69, 71, 73-74). Waugh et al. further teach that other cosmetic agents can be antioxidants and vitamins (p. 15 lines 20-34; claims 70, 72).

Response: The Illum reference has been withdrawn in view of Applicants' amendments and remarks. However, the instant claims are believed to be unpatentable over the newly cited Waugh et al. reference for the reasons noted above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-69, 71, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51-55, 64-73, 77-118, 146, 149-150 of copending Application No. 10591732 ('732). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '732 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The botulinum toxin of the '732 application would be considered a biologically active protein since botulinum toxin is an antiwrinkle agent (recited in instant claim 67). Additionally, the '732 specification discloses that the positively charged branching groups can be selected from HIV-TAT fragments; therefore, the carrier recited in the '732 claims has the same structural features as the carrier recited in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

Claims 67-69, 72-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-80, 84, 90-94 of copending Application No. 10591485 ('485). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '485 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged

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branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The biologically active protein which does not therapeutically alter blood glucose levels of the '485 application would be considered a biologically active protein (recited in instant claim 67). Additionally, the '485 specification discloses that the positively charged branching groups can be selected from HIV-TAT fragments; therefore, the carrier recited in the '485 claims has the same structural features as the carrier recited in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 67-69, 71, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 12647677 ('677). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '677 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The botulinum toxin of the '677 application would be considered a biologically active protein since botulinum toxin is an antiwrinkle agent (recited in instant claim 67). Further, claim 10 of the '677 application recites that the treatment is for wrinkles, which one of ordinary skill would know could be considered a topical application. Additionally, the '677 specification discloses that the positively charged branching groups can be selected from

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HIV-TAT fragments; therefore, the carrier recited in the '677 claims has the same structural features as the carrier recited in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 67-69, 71, 73-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11 of copending Application No. 11816602 ('602). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '602 claims are drawn to a method of topically applying to the skin or epithelium of a subject, a composition comprising a carrier which has a polymeric backbone having positively charged branching groups and a biologically active protein, wherein the carrier and the biologically active protein associate non-covalently. The botulinum toxin of the '602 application would be considered a biologically active protein since botulinum toxin is an antiwrinkle agent (recited in instant claim 67). While the composition of the '602 application can comprise at least one member selected from the group consisting of a partitioning agent, oligo-bridge, and polyanion bridge, it should be noted that the use of open claim language "comprising" in instant claim 67 does not preclude additional ingredients. Additionally, the '602 specification discloses that the positively charged branching groups can be selected from HIV-TAT fragments; therefore, the carrier recited in the '602 claims has the same structural features as the carrier recited in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response: Applicants' remarks regarding the provisional obviousness-type double patenting rejections are acknowledged.

The provisional obviousness-type double patenting rejections are maintained herein since there are other issues raised in the instant Office action, in addition to the provisional obviousness-type double patenting rejections.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 29, 2010

M. Tsay  
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/Manjunath N. Rao /  
Supervisory Patent Examiner, Art Unit 1656